UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON; D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 9, 2015

MEMORANDUM

SUBJECT: Efficacy Review for VBC-60394 Biological Larvicide Fine Granule, a New Pesticide Product Containing the Active Ingredients *Bacillus thuringiensis* subsp. israelensis strain AM65-52 and S-methoprene

EPA File Symbol: 73049-LNR
MRID: 494061-12
Decision №: 492184
DP №: 421291
Submission: 953575

FROM: Kathleen Martin, Chemist, M.S.E.S. K.M. 2/9/15
Microbial Products Branch
Biopesticides and Pollution Prevention Division

THROUGH: Shannon Borges, Team Leader
Microbial Products Branch
Biopesticides and Pollution Prevention Division 2/9/15

TO: Kenneth Haymes, Regulatory Action Leader
Microbial Products Branch
Biopesticides and Pollution Prevention Division

Action Requested. Valent BioSciences Corporation has applied to the Agency for registration of a new pesticide product containing *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 (PC Code 069162) and S-methoprene (PC Code 105402). This product, VBC-60394, is an insecticide for use against mosquito larvae. Provided in the attached Data Evaluation Record is a review of the submitted efficacy data.

Attachment: Data Evaluation Record

pc: Cheryl Greene, Biopesticides Branch Biopesticides and Pollution Prevention Division

Data Evaluation Record

Reviewed by:	Kathleen Martin, M.S.E.S.	**Date:**	February 9, 2015
Secondary Review:	Shannon Borges, M.S.		

STUDY TYPE:	Product Performance (Efficacy)
DATA REQUIREMENT:	40 CFR 158.2160
TEST GUIDELINE:	Not applicable
MRID:	494061-12
DP BARCODE:	421291
DECISION №:	492184
SUBMISSION:	953575
TEST MATERIALS:	*Bacillus thuringiensis israelensis*, Serotype H-14, strain AM65-52 S-Methoprene
REPORT TITLE:	Product Performance: Efficacy of VBC-60394. Data Requirements: 40 CFR § 158.2160 Product Performance. DeChant, Peter and Clark, Jason. Valent BioSciences® Corporation. Valent Project ID: VBC-60394 EFF. February 16, 2014[1].
AUTHORS:	Peter DeChant and Jason Clark
SPONSOR:	Valent BioSciences Corp.
TESTING FACILITY:	Not provided
PROJECT ID:	VBC-60394 EFF
STUDY DATE:	February 16, 2014
RECEIPT DATE:	June 13, 2014
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	The information contained in this document was not conducted under the requirements of GLP (40 CFR 160); it is a presentation and summation of field efficacy trails.
STUDY SUMMARY AND CONCLUSION:	VBC-60394 was effective in reducing the number of larvae and emerging adults for most of the species tested when used at recommended label rates. Higher applications may be required for deeper water and for applications made pre-flood.
DEFICIENCIES:	None
CLASSIFICATION:	ACCEPTABLE

Valent's VBC-60394 Biological Larvicide Fine Granule (EPA File Symbol 73049-LNR) is an insecticide for use in killing mosquito larvae. The product contains two pesticide active ingredients:

① *Bacillus thuringiensis* subsp. israelensis strain AM65-52 (PC Code 069162), 6.07%; and

② S-methoprene (PC Code 105402); 0.10% (MRID 494061-01)

[1]The deficiencies in this study were addressed in a letter from Valent (2014b).

Because this product claims to control a public health pest "that may directly or indirectly transmit diseases to humans," the Agency requires the submission of efficacy data.

PROPOSED USE PATTERN (from Draft Label)

VBC-60394 Biological Larvicide Fine Granule is an insecticide for use against mosquito larvae. The proposed use pattern is:

Mosquitoes Habitat: (irrigation ditches, standing ponds, etc.)	1.25 to 20.0 lb/A
Post-Flood: (e.g., heavily polluted water such as sewage and waste lagoons)	4.0 to 10.0 lb/A
Pre-Flood:	10 to 20 lb/A

DESCRIPTION OF TRIALS USED TO ASSESS EFFICACY

Valent conducted six trials using simulated microcosms to assess the efficacy of VBC-60394. They: used three species of mosquito larvae, each with a distinct habitat and range; considered pre-and post-flood conditions, and various application rates. Provided in Table 1 is a summary of the data used in the Trials; the key parameters are discussed below. Note that the Trials are tabulated by species, which is the reason why the Trial numbers are not in numerical order. Following Table 1 are more detailed descriptions of the methodology that Valent used in each of the trials.

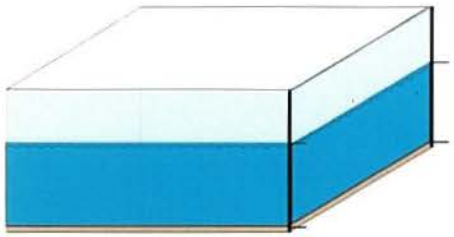

Figure 1 Schematic of a Simulated Microcosm

Test Location: Trials were conducted in Riverside California; or Yakima Washington.

Test Substance and Concentration: VBC-60394

Test Species: A*edes taeniorhynchus* (A. *taeniorhynchus)*; *Aedes vexans* (A. vexans); *Culex quinquefasciatus* (C. *quinquefasciatus*); and *Culex pipiens* (*C. pipiens*).

Life Stage: The egg and larval part of a mosquito's life cycle is often described using the term 'instar,' where egg-laying occurs during the 1st instar and 2nd instar (L1, L2) and development of larvae occurs in the 3rd and 4th instar (L3, L4).

Habitat and Range: A*edes taeniorhynchus* are salt marsh mosquito found on the "coastal plains from Massachusetts to Texas, in California along the Pacific Coast and in the Caribbean" (Rutgers 2013a). *Aedes vexans* are found in "virtually any transient waters…but rainpools in unshaded areas produce the largest broods." These mosquitoes are found in every state including Alaska and Hawaii (Rutgers 2013b). *Culex quinquefasciatus* (C. *quinquefasciatus*) and *Culex pipiens* (C. *pipiens*) are part of the the *Culex pipiens* complex; they are commonly referred to as "house mosquitoes (Rutgers 2013c). "House mosquitoes are common in urban and suburban communities as well as on rural premises. Members of the complex readily breed in storm sewer catch basins, clean and polluted ground pools, ditches, animal waste lagoons, effluent from sewage treatment plants and other sites that are slightly to very eutrophic or polluted with organic wastes" (Rutgers 2013c).

Surface Area of Microcosms: The reported surface areas of the microcosm were calculated based on the interior dimensions of the tub (Valent 2014b).

Water Depth: Between 6 to 10 inches, except for Trial 2013PDECH015 where three depths (ranging from 12 to 33 inches. Valent (2014b) ran Trial -15 to observe the impact of water depth on efficacy of VBC-60394.

Organic Enrichment: As a food source for the developing larvae, study investigators added rabbit pellets to the simulated ecosystems[2] at either 0.0125%, 0.039%, or 0.05%. The enrichment concentrations differed among the Trials because the laboratory-reared mosquitos (those in Trials 2013PDECH0-10 and -23) do not need highly enriched waters.

Salinity: The water used it Trials 2013PDECH0-10 and -14 was salinized (0.3%) because of the habitat of *A. taeniorhynchus* mosquitoes—they are found in salt marshes.

Flood Water: Tap water was used for all trials. In Trials -15 and -23 which were conducted using polluted water." For this study, Valent (2014b) sought to mimic "polluted water" by adding rabbit pellets and straw to each microcosm "to attract oviposition by *Culex* mosquitoes.

Table 1 Summary of the Six Efficacy Trails

	A. taeniorhynchus		***A. vexans***		***Culex pipiens* complex**	
Trial Number:	2013PDECH010	2013PDECH014	2013PDECH011	2013PDECH025	2013PDECH015	2013PDECH023
Test Location:	CA		WA		CA	WA
Start Date:	June 24, 2013	June 27, 2013	July 12, 2013	August 28, 2013	August 31, 2013	July 30, 2013
Test Substance:	VBC-60394 (30-053-VB)		VBC-60394 (Lot 30-053-VB)		VBC-60394 (Lot 30-058-VB)	VBC-60394 (30-053-VB)
Test Substance Concentration:	6.07 % *Bacillus thuringiensis* subsp. israelensis strain AM65-52 (PC Code 069162), and 0.10% S-methoprene (PC Code 105402); 0.10% (MRID 494061-01)					
Application Rate (lb/A):	5.0	10 or 20	1.25, 2.5, or 5.0	15	5.0	2.5, 5.0, or 10
Test Species:	*A. taeniorhynchus* larvae (lab-reared)		*A. vexans* larvae (field-collected)		*C. quinquefasciatus* larvae (natural infestation)	*C. pipiens* larvae (natural infestation)
Life Stage (L):	L3	late L2	L3	L1, L2	L3	Mixed L2 and L3
Species Habitat:	coastal plain salt marshes		any transient waters; they breed most prolifically in rainpools in unshaded areas.		storm sewer catch basins, clean and polluted ground pools, ditches, animal waste lagoons, effluent from sewage treatment plants	
Species Range:	Massachusetts to Texas and the Pacific Coast		entire Continental U.S. and Alaska & Hawaii		a very common mosquito across the US; it is found in urban to rural areas.	
Surface Area (ft^2) of Tubs:	4.17		3.11	3.11	3.76	3.11
Water Depth (in):	10		6		12 24 33	6

[2]**NOTE:** Valent clarified these data (Valent 2014b)

Surface Area of Microcosms: The reported surface areas of the microcosm were calculated based on the interior dimensions of the tub (Valent 2014b).

Water Depth: Between 6 to 10 inches, except for Trial 2013PDECH015 where three depths (ranging from 12 to 33 inches. Valent (2014b) ran Trial -15 to observe the impact of water depth on efficacy of VBC-60394.

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Salinity: The water used it Trials 2013PDECH0-10 and -14 was salinized (0.3%) because of the habitat of *A. taeniorhynchus* mosquitoes—they are found in salt marshes.

Flood Water: Tap water was used for all trials. In Trials -15 and -23 which were conducted using polluted water." For this study, Valent (2014b) sought to mimic "polluted water" by adding rabbit pellets and straw to each microcosm "to attract oviposition by *Culex* mosquitoes.

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Test Species:	*A. taeniorhynchus* larvae (lab-reared)		*A. vexans* larvae (field-collected)		*C. quinquefasciatus* larvae (natural infestation)	*C. pipiens* larvae (natural infestation)
Life Stage (L):	L3	late L2	L3	L1, L2	L3	Mixed L2 and L3
Species Habitat:	coastal plain salt marshes		any transient waters; they breed most prolifically in rainpools in unshaded areas.		storm sewer catch basins, clean and polluted ground pools, ditches, animal waste lagoons, effluent from sewage treatment plants	
Species Range:	Massachusetts to Texas and the Pacific Coast		entire Continental U.S. and Alaska & Hawaii		a very common mosquito across the US; it is found in urban to rural areas.	
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Water Depth (in):	10		6		12 24 33	6

[2]**NOTE:** Valent clarified these data (Valent 2014b)

	A. taeniorhynchus		***A. vexans***		***Culex pipiens* complex**	
Trial Number:	2013PDECH010	2013PDECH014	2013PDECH011	2013PDECH025	2013PDECH015	2013PDECH023
Volume of Water (gal)	26		11.7	11.7	28.2 56.4 77.55	11.7
Soil-Lined Tubs?	YES (0.5 inches)		YES (0.5 inches)	YES (1 inch)	NO	YES (1 inch)
Organic Enrichment:	0.0125%		0.039%	0.039%	0.05%	0.039%
Salinity:	0.3%		--	--	--	--
Flood Stage:	Post-flood	Pre-flood (at Day 2 or 7)	Post-flood	Pre-flood (at Day 10)	Post-flood	Post-flood
Water Temp (F°) During Treatment:	min: 64 to 74 max: 89 to 97	min: 60 to 64 max: 82 to 88	not provided	min: 49 to 64 max: 81 to 94	min: 76 to 79 max: 86 to 96	not provided

Description of the Six Trials

Aedes taeniorhynchus

2013PDECH010: efficacy of VBC-60394 against lab-reared 3rd instar *A.taeniorhynchus* larvae when applied post-flood at 5.0 lb/A.

To simulate a field microcosm environment, study investigators used sand-lined plastic tubs with water that was enriched to promote growth of the test organisms. The bottom of each was lined with sandy loam soil that was collected from the test site. After the tubs were flooded with tap water, rabbit pellets and table salt were added. A minimum-maximum thermometer was put at bottom of one tub to monitor water temperature range during each sampling interval.

Once the water settled for a day, fifty L3 *Aedes taeniorhynchus* larvae were added to each tub (treatment and control) and allowed to acclimate for one hour. Then, the microcosm was treated with VBC-60394 at a rate of 5.0 lb/A. Study investigators used four replicates for the treated microcosm and four as a control (i.e., untreated microcosm).

At 24 and 48 hours post-treatment surviving larvae were counted. After that, all pupae were removed daily. They were held in a cup (at 80 to 85 °F) until all pupae died or emerged. Partially emerged adults with legs and/or wings attached to the exuviae were considered dead. Inhibition of Emergence (IE) was used to evaluate the outcome of adult production. Percentage reduction (mortality) was calculated using simplified Mulla's formula and analyzed by using Chi-square test; %IE was calculated as:

$$\%IE = \frac{number\ pupae\ collected - number\ free\ exuviae}{number\ pupae\ collected} \times 100$$

TRIAL 2013PDECH014: Efficacy of VBC-60394 against lab-reared late 2nd instar *A. taeniorhynchus* when applied pre-flood on Day 7 or 2 at 10 and 20 lb/A.

To simulate a field microcosm environment, study investigators used soil-lined plastic tubs that were filled with water that had been enriched to promote growth of the test organisms. The bottom of each was lined with sandy loam soil that was collected from the test site which was allowed to sun-dry for one day before treatment; to facilitate drying, the soil was stirred twice during the drying period.

On Day 7 (or Day 2[3]) prior to flooding, each of the test materials were evenly spread onto the top of the dry soil at 10 lb/A and 20 lb/A. Four replicates were set up for each material and each application rate combination; additionally four replicates for the untreated control. After treatment, the temperature of the soil was recorded daily using a minimum-maximum thermometer.

Once the tubs had been exposed to the natural environment for seven (or two) days, they were flooded by tap water in a gentle manner so as to avoid disruption of the test material; water volume was maintained by daily replenishment. Rabbit pellets salt were then added. A minimum-maximum thermometer was put at bottom of one tub to monitor water temperature range during each sampling interval.

Two hours after 50 laboratory-reared late L2 *A. taeniorhynchus* larvae were added to each tub (treatment and control). After 96 hours, surviving larvae were retrieved (from treated and untreated tubs) and counted to evaluate initial larvicidal efficacy; they were then returned to their respective tubs. On Days 8 and 11 post-flood, pupae were removed and held in small containers (corresponding to their respective tub) until all pupae died or emerged; water temperature in the containers ranged from 80 to 85°F. Partially emerged adults with legs and/or wings attached to the exuviae were considered dead. Inhibition of Emergence (IE) was used to evaluate the outcome of adult production.

Percentage reduction (mortality) at 96 hours post-introduction was calculated using simplified Mulla's formula and analyzed by using Chi-square test; %IE was calculated as:

$$\%IE = \frac{number\ pupae\ collected - number\ free\ exuviae}{number\ pupae\ collected} \times 100$$

[3]This assay was conducted using two pre-flood intervals: 7 and 2 days. For each interval, the test material was applied at 10 lb/A and 20 lb/A.

Aedes vexans

2013PDECH011: Efficacy of VBC-60394 against field-collected 3rd instar *A. vexans* when applied post-flood at 1.25 to 5.0 lb/A.

To simulate a field microcosm environment, study investigators used soil-lined plastic tubs with organic-enriched water. After the tubs were allowed to stabilize for 24 hours, 100 to 250 field-collected L3 *A. vexans* larvae were added to each and allowed to acclimate for two hours. Then, the tubs were treated with VBC-60394 at 1.25, 2.5, or 5.0 lb/A using four replicates per treatment; four untreated tubs were set up as an untreated control.

The microcosms were evaluated 24 and 48 hours post-treatment by counting the number of surviving larvae and pupae. Means of larval counts and percent mortality were calculated for each treatment. Surviving larvae were allowed to develop into pupae. At 96 hours, pupae were collected from the tubs and up to 25 per tub were placed in a covered quart jar. The total number of adults emerging from those jars was counted. Inhibition of Emergence (IE) was calculated using the following formula:

$$\%IE = 1 - \frac{number\ emerged\ adults}{total\ number\ pupae\ in\ jars} \times 100$$

2013PDECH025: Efficacy of VBC-60394 against field-collected 3rd instar *A. vexans* when applied pre-flood at 15 lb/A.

To simulate a field microcosm environment, study investigators used soil-lined plastic tubs that dad been treated with VBC-60394 at 15 lb/A; the tubs were placed outdoors for 10 days in direct sunlight. The tubs were then flooded and rabbit pellets were added as organic enrichment. Two hours later, 75 to 100 L1 and L2 larvae were added.

Populations were sampled 24, 48, 72 and 96 hours after larvae were placed in tubs by taking two dips per tub with a standard mosquito dipper and estimating the number of larvae per dip. At 144to 192 hours after larval placement, pupae were collected wherever possible. Up to 25 pupae were collected from each tub and place in one quart jars with lids. The total number of adults emerging was counted. The inhibition of emergence (IE) was calculated using the following formula:

$$\%IE = 1 - \frac{number\ successful\ emerged\ adults}{total\ number\ pupae} \times 100$$

Culex pipiens complex

2013PDECH015: Efficacy of VBC-60394 against natural infestation by 3rd instar *Culex quinquefasciatus* when applied post-flood to polluted at a rate of 5.0 lb/A and three depths.

To simulate a field microcosm environment, study investigators used water-filled plastic tubs. Three water depths were used to observe the impact of water depth on efficacy of the formulations tested (Valent 2014b). A minimum-maximum thermometer was put at bottom of one tote to monitor water temperature. After flooding, rabbit food was added to each tote to promote growth of the test organisms. The tubs were allowed to become naturally infested with *Culex quinquefasciatus* mosquito larvae. When larvae had reached the L3, the microcosms were treated with test material at a rate of 5 lb/A. Study investigators ran replicates at each depth in addition to four replicates of untreated control at each depth.

Investigators assessed the tubs prior to treatment and at 24 and 48 hours post-treatment—they counted the number of live larvae and pupae. During treatment Days 3 to 5 (i.e., after 48 hours), surviving larvae were allowed to pupate; up to 25 from each tub were isolated and were monitored until they died. The determinant for successful emergence was empty exuviae. Completely empty exuviae was counted as success while dead pupae and partially emerged adults was considered as emergence failure. Average counts for early instars, late instars, and pupae were calculated per dip; these were used in an ANOVA analysis to determine greatest efficacy among the three water depths. The percent of the isolated pupae (for each isolation group) that fully emerged was calculated as:

$$\%\ Fully\ Emerged\ Adults = \frac{number\ of\ exuviae}{number\ of\ pupae}$$

And percent inhibition of emergence:

$$\%IE\ = 1 - \frac{number\ emerged\ adults}{total\ number\ pupae\ isolated} \times 100$$

2013PDECH023. Efficacy of VBC-60394 against natural infestation of mixed instar *Culex pipiens* when applied post-flood to polluted water at a rate of 1.25 to 5.0 lb/A.

To simulate a field microcosm environment, study investigators used soil-lined plastic tubs and organic-enriched water to which a small amount of straw was added to simulate a natural *Culex* habitat. Tubs were left outdoors until they were naturally infested with *Culex pipiens* larvae. When larvae were primarily in the 2nd and L3 stage, the microcosms were treated with the test material at a rate of 2.5 lb/A, 5.0 lb/A, or 10 lb/A. Investigators counted the number of larvae per tub prior to application and at 24 and 48 hours post-treatment. After 48 hours, surviving larvae were allowed to develop into pupae in each tub; 25 pupae from each tub were isolated to measure % emergence of adults.

$$\%IE\ = 1 - \frac{number\ emerged\ adults}{total\ number\ pupae\ isolated} \times 100$$

RESULTS (2013PDECH-0XX)

For *A. taeniorhynchus* and *A. vexans* pre- and post-flood Trials were conducted. The *A. vexans* Trial was run at two application rates and two pre-flood intervals. Provided in Table 2 are the post-flood results and in Table 3, the pre-flood.

Table 2 Post-Flood: % Larval Reduction and % Adult Suppression

	-010	**-011**	**-015**	**-023**
Species:	*A. taeniorhynchus*	*A. vexans*	*C. quinquefasciatus*	*C. pipiens*
Life Stage:	L3	L3	L3	L2, L3
Water Depth (in):	10	6	12, 24, or 33	6
Application Rate (lb/A)	5.0	1.25, 2.5, or 5.0	5.0	2.5, 5.0, or 10
% Larval Reduction (at 48 hours):	98.5	1.25 lb/A: 88.0 2.5 lb/A: 97.0 5.0 lb/A: 100	12 in: 99.5 24 in: 96.0 33 in: 18.6	2.50 lb/A: 99.0 5.0 lb/A: 100 10.0 lb/A: 100
% Adult Suppression	100 % (no pupae developed)	1.25 lb/A: 96 2.5 lb/A: 98 5.0 Lb/A: 100	12 in: 99.7 97.6 in: 97.6 39.8 in: 39.8	2.50 lb/A: 100 5.0 lb/A: 100 10.0 lb/A: 100

For post-flood application, VBC-60394 appears to be efficacious among several the larvae of several species of mosquito larvae including *Culex pipiens* complex, which is the common house mosquito when used at rates between 1.25 and 5.0 lb/A and water depths between 6 and 24 inches.

Table 3 Pre-Flood: % Larval and Pupal Reduction

	-014	**-025**
Species:	*Aedes taeniorhynchus*	*Aedes vexans*
Life Stage:	late L2	L1, L2
Flood Stage:	pre (at Day 2 or 7)	pre (at Day 10)
Water Depth (in):	10	6
Application Rate (lb/A)	10 or 20	15
% Larval Reduction at 96 hours post-infestation:	Day 2; 10 lb/A: 100 Day 2; 20 lb/A: 100 Day 7; 10 lb/A: 100 Day 7; 20 lb/A: 100	56
% Pupal Reduction 144+ Hours	Day 2; 10 lb/A: 100 Day 2; 20 lb/A: 100 Day 7; 10 lb/A: 100 Day 7; 20 lb/A: 100	88

DISCUSSION

Study Design: Study investigators used simulated field microcosms to test the efficacy of VBC-60394 against four species of mosquito larvae (*A. taeniorhynchus*, *A. vexans*, *C. quinquefasciatus*, and *C. pipiens*). They species chosen represent a wide range of mosquitoes found in the U.S.—from those that thrive in coastal salt marshes (*A. taeniorhynchus*) to the common house mosquito (*Culex pipiens* complex) and the test conditions reflected the species. For example, *A. taeniorhynchus* are found in salt marshes so the water used in those trials was salinized. The surface areas of the tubs ranged from 3.1 to 4.2 ft^2. A range of application rates were used and one Trial looked at the efficacy of VBC-60394 at three different depths. The studies were conducted in Riverside California and Yakima Washington, which are both in temperate climate zones (USDA Zone 9).

Statistics and Data Analysis: Investigators used four replicates per Trial. In Trials where different application rates or water depths were investigated, four trials were used for each rate or depth. Appropriate statistics were used to characterize the variability among replicates and the % reduction and suppression.

Polluted Waters: The study did not adequately characterize the term and efficacy of "polluted water." In Trial -23, investigators mimicked polluted water by adding straw to the tubs and rabbit pellets. The Ecological Society of America (2009) asserts that mosquitoes thrive in sewage-contaminated waterways. They found that "mosquitoes were largest in streams with high levels of organic minerals such as nitrogen and phosphorus." Addition of straw and rabbit pellets do not adequately describe what is meant by pollution.

Overall Results: VBC-60394 was effective in reducing the number of larvae and emerging adults for most of the species tested when used at recommended label rates. Higher applications may be required for deeper water and for applications made pre-flood. The proposed label indicates that higher rates are needed for waters that are more polluted, such as those that are habitat for *C. vexans*, and for 7-14 day pre-flood applications, which should increase efficacy. The label also instructs the user to treat according to local conditions or when local experience indicates that greater application rates are needed, and allows for retreatment when necessary, which should lead to sufficient efficacy under a range of conditions.

REFERENCES

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Rutgers. 2013a. The black salt marsh mosquito *Aedes taeniorhynchus*. Apperson, Charles. Rutgers University School of Environmental Science and Biological Sciences. http://www-rci.rutgers.edu/~insects/sp10.htm. Webpage last modified: March 18, 2013. lreed@rci.rutgers.edu.

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U.S. EPA. 2014. Letter from Shannon Borges, U.S. Environmental Protection Agency Biopesticides and Pollution Prevention Division to Jayne Walz, Valent Biosciences Corporation. RE: OPP Decision No.: D-492184. Data Deficiency Screen for new biological larvicide. VBC60394 Biological Larvicide. EPA File Symbol: 73049-LNR. Application for Registration Dated June 11, 2014. December 4, 2014.

Valent. 2014a. Product Performance: Efficacy of VBC-60394. Data Requirements: 40 CFR § 158.2160 Product Performance. DeChant, Peter and Clark, Jason. Valent BioSciences® Corporation. Valent Project ID: VBC-60394 EFF. February 16, 2014. U.S. EPA MRID 494061-12.

Valent. 2014b. Letter from Jayne Walz, Regulatory Manager Valent BioSciences® Corporation to Kenneth Haymes U.S. Environmental Protection Agency. RE: Valent BioSciences Response to EPA's 75-Day Letter for VBC-60394 Biological Larvicide (EPA File Symbol: 73049-LNR) Decision Number: D-429184. December 18, 2014.